DEC 7 2005

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Smith & Nephew, Inc.
Summary of Safety and Effectiveness
Smith & Nephew Modular Hip Line Additions

Contact Person and Address
Jason Sells
Regulatory Affairs Specialist
Smith & Nephew, Inc.
Orthopaedic Division
1450 Brooks Road
Memphis, TN 38116
(901) 399-5520

Date of Summary: September 1, 2005

Name of Device: Smith & Nephew Modular Hip
Common Name: Prosthetic hip joint

Device Description
The Smith & Nephew Modular Hip consists of primary and revision stems used with porous and HA coated modular sleeves. The stems feature a 12/14 taper and are used with existing Smith & Nephew femoral heads and acetabular components. Modular hip stems and sleeves are manufactured from Ti-6Al-4V conforming to ASTM F 1472 or ASTM F 136.

Device Classification
21 CFR 888.3353 Hip joint metal/ceramic/polymer semi-constrained cemented or nonporous uncemented prosthesis – Class II

Mechanical and Clinical Data
A review of the mechanical test data indicated that the Smith & Nephew Modular Hip is equivalent to devices currently used clinically and is capable of withstanding expected *in vivo* loading without failure.

Indications for Use
Total hip components are indicated for uncemented use in individuals undergoing primary and revision surgery where other treatments or devices have failed in rehabilitating hips damaged as a result of trauma, inflammatory joint disease such as rheumatoid arthritis, or noninflammatory degenerative joint disease (NIDJD) or any of its composite diagnoses such as osteoarthritis; avascular necrosis; traumatic arthritis; slipped capital epiphysis; fused hip; fracture of the pelvis; diastrophic variant; old, remote osteomyelitis with an extended drainage-free period; nonunion, femoral neck fracture and trochanteric fractures of the proximal femur with head involvement that are unmanageable using other techniques; femoral osteotomy, or Girdlestone resection; fracture dislocation of the hip; and correction of deformity. Smith & Nephew Modular Hip components are for single use only.

Substantial Equivalence Information
The substantial equivalence of the Smith & Nephew Modular Hip is based on its similarities in indications for use, design features, operational principles, and material composition to the following predicate devices – Joint Medical Products S-ROM Total Hip System (K921111, K934412, K954935, and K961939), the Smith & Nephew Synergy Hip System (K963509, K991485, and K002996), and the Smith & Nephew Modular Hip System (K042127). The subject devices are line addition components to the Smith & Nephew Modular Hip System cleared via K042127.

Standards Data Form for Abbreviated 510(k)s

510(k) Number: K052426

Standard Organization No:
or
Standard Identification No: ISO 7206-4 (1987)
ASTM #1472, ASTM F67
ASTM #136
or
CDRH Internal Reference No:

Declaration of Conformity Elements:		
Any Adaptations Applied	yes	(no)
Any Requirements Not Applicable	yes	(no)
Any Deviations Applied	yes	(no)
Any Differences in Device Tested and Finished Product	yes	(no)
*Is There a Third Party or Test Lab Involved	yes	(no)

Was there another standard used in the review of this submission? yes no

If another standard was used, please fill out an additional form.

* This is not the third party that reviews 510ks

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

DEC 7 2005

Jason Sells
Regulatory Affairs Specialist
Smith &Nephew, Inc
Orthopaedic Division
1450 Brooks Road
Memphis, Tennessee 38116

Re: K052426
Trade/Device Name: Smith & Nephew Modular Hip
Regulation Number: 21 CFR 888.3353
Regulation Name: Hip joint metal/ceramic/polymer semi-constrained cemented or nonporous uncemented prosthesis
Regulatory Class: II
Product Code: MEH
Dated: November 29, 2005
Received: November 30, 2005

Dear Mr. Sells:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

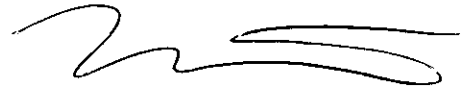
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,



for Mark N. Melkerson
Acting Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K052426

Device Name: Smith & Nephew Modular Hip

Indications for Use:

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Prescription Use (Part 21 CFR 801 Subpart D)	X	AND/OR	Over-The-Counter Use (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of General, Restorative, and Neurological Devices

510(k) Number K052426